

REMARKS

This is a supplemental response to the Final Rejection dated February 8, 2006, (hereinafter the “Final Rejection”) and the Advisory Action dated April 12, 2006 (hereinafter the “Advisory Action”).

In the Advisory Action, the Examiner made the following comment:

“The request for reconsideration has been considered but does NOT place the application in condition for allowance because Applicant’s arguments are not persuasive for reasons of record.... In regards to the arguments, the claims language with respect to radiation uses ‘comprising’ which is open to all other types of radiation such as UV. [The] Examiner believes there is sufficient overlap of the various claimed ionizing radiation with UV radiation to suggest a case of obviousness.”

Advisory Action, paragraph 11.

This rationale is valid only if the Examiner has presented a case of *prima facie* obviousness against the claimed subject matter for treatment of radiation injury due to ionizing UV radiation. However, the Examiner has not made out a *prima facie* case of obviousness for the claimed subject matter for treatment of radiation injury due to ionizing UV radiation for the reasons given below.

The Health Physics Society, specialists in radiation safety, indicate that vacuum UV radiation having wavelengths of 40-124 nm, may be characterized as ionizing radiation. See Exhibit 1. Apparently, this is the basis for the Examiner’s conclusion that there is overlap between UV radiation and ionizing radiation.

However, based on the teachings of Kita, a skilled person would not employ vitamin D compounds as a blocking agent against any type of ionizing radiation, even if such ionizing radiation were UV radiation having a wavelength of 40-124 nm. This is because Kita relies on absorption of radiation by the vitamin D compounds and Kita clearly teaches that vitamin D compounds absorb radiation in the 240-290 nm range. See col. 1, lines 25-29, col. 6, lines 17-29 and col. 8, lines 49-62 of Kita. As a result, vitamin D compounds would not be considered useful as a blocking agent against ionizing UV radiation since ionizing UV radiation has a wavelength of 40-124 nm, which is far outside the range of wavelengths that are absorbed by vitamin D compounds, as taught by Kita.

In addition, it is clear from the teachings of Kita, that Kita is only concerned with non-ionizing UV radiation since Kita only discusses injury caused by UV radiation in the wavelength

ranges of 200-315 nm, which is far outside the wavelength range of ionizing UV radiation of 40-124 nm. See col. 2, lines 44-59 of Kita.

Moreover, Kita teaches topical use of vitamin D compounds to absorb UV radiation. The UV radiation is absorbed because the vitamin D compounds are located between the body and the source of radiation. The present claims relate to oral administration of the composition, in which case the vitamin D₃ is not located between the source of radiation and the body. As a result, the skilled person would have no expectation of success for oral administration of vitamin D₃ from the teachings of Kita, since Kita teaches that the vitamin D compounds should be located between the source of radiation and the body in order to absorb the radiation and, in the case of oral administration, the vitamin D compounds are not located between the source of radiation and the body, but rather, are located inside the body.

Kita, in summarizing the prior art, mentions that therapeutic vitamin D may be administered orally or by injection. See col. 1, lines 42-44 of Kita. However, the prior art oral administration is not for the purpose of treating radiation injury, but rather, is for the purpose of treating one or more of, "...rickets, osteomalacia, osteoporosis, osteitis, fibrosa, osteosclerosis and other bone diseases, malignant tumors such as breast and colon cancers..." See col. 1, lines 15-24 of Kita. Again, this provides the skilled person with no teaching or suggestion that oral administration of vitamin D would have any beneficial effect in the treatment of radiation injury. That Kita is limited to topical application of vitamin D compounds is confirmed by the title of Kita, which reads, "**External** Ophthalmic Preparation Containing Vitamin D." From this, it is clear that Kita does not teach or suggest the internal administration of Vitamin D, as in the present invention.

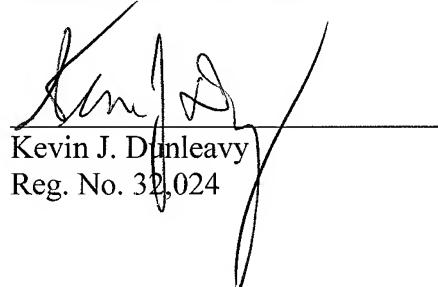
With regard to U.S. Patent no. 5,686,082 (hereinafter "Nguyen"), this patent is clearly concerned with exposure to atmospheric ultraviolet radiation that causes skin ageing. See e.g. col. 1, lines 18-26 of Nguyen where Nguyen states, "These harmful effects are exerted in particular on the cells of the skin and of the mucous membranes in contact with the external environment." (emphasis added). Col. 5, lines 25-54 of Nguyen also relate to this point. The same is true of U.S. Patent no. 5,141,741 (hereinafter "Ishida, et al."), which is entitled, "Anti-Sunburn Skin-Care Preparation."

The article "Sunburn" by James Foster, MD, MS, of the Alverado Hospital Medical Center (12 pages) found at <http://www.emedicine.com/EMERG/topic798.htm> (enclosed herewith

as Exhibit 2) points out on page 5 that UV radiation that reaches the earth has wavelengths of 290-400 nm and that UV radiation having wavelengths below 290 nm is filtered out or absorbed in the outer atmosphere and is not encountered at sea level. In view of this fact, the skilled person would be led to conclude that neither Ishida et al. nor Nguyen would be useful for the treatment of injury due to ionizing UV radiation having a wavelength of 40-124 nm since ultraviolet radiation from the sun or outer space having wavelengths of 40-124 nm does not pass through the outer atmosphere of the earth. Accordingly, a skilled person would not apply the teachings of either Nguyen or Ishida et al. to treat radiation injury due to ionizing radiation since it would be clear to a skilled person that the teachings of Nguyen and Ishida et al. are limited to non-ionizing UV radiation encountered in the environment, which would not include ionizing radiation which has been filtered out by the atmosphere.

For the reasons given in the complete response to the Final Rejection filed on 31 March 2006, and the additional reasons given herein, the claims of the present application are considered to be in condition for immediate allowance. Favorable consideration and issuance of a Notice of Allowance is requested.

Respectfully submitted,

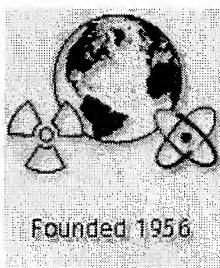


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Enclosures: Exhibits 1-2 as discussed in the text of this Supplemental Response.



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Answer to Question #2111 Submitted to "Ask the Experts"

Category: Suntanning

The following question was answered by an expert in the appropriate field:

Q: *On a Web site, I've found frequency specs claiming that UV light is also ionizing. Is this correct and does that mean that it can penetrate deep into a human body if overexposed (say on a tanning bed)?*

A: Recall that ultraviolet (UV) radiation is defined as that portion of the electromagnetic spectrum between x rays and visible light, i.e., between 40 and 400 nm (30-3 eV). The UV spectrum is divided into Vacuum UV (40-190 nm), Far UV (190-220 nm), UVC (220-290 nm), UVB (290-320), and UVA (320-400 nm). Visible light is in the nonionizing portion of the electromagnetic spectrum; x rays are in the ionizing portion. UV is in between.

The term ionizing radiation refers to radiation with sufficient energy to produce ionizations in a medium. The energy threshold is not precisely defined as it depends on the composition and phase of the medium. One energy threshold that is sometimes quoted is 10 electron volts (eV), which would mean that UV radiation with wavelengths shorter than 124 nanometers (nm) (mid-Vacuum UV) is ionizing radiation. Another characterization would be to say that the higher-energy (shorter-wavelength) portion of the UV spectrum can be considered ionizing radiation and the lower-energy (longer-wavelength) portion, nonionizing. Intermediate UV energies may be considered ionizing or nonionizing depending on the specifics of the materials and endpoints being measured.

UV radiation does not penetrate deeply in the body. Nor for that matter do low-energy x rays, which are also ionizing radiations. The ability to penetrate deeply into the body does not begin until the energy of the x rays is much higher, on order 50,000 eV and above.

Gary Zeman, ScD, CHP
Lawrence Berkeley National Laboratory

Answer posted on April 9, 2003. The information and material posted on this Web site is intended

as general reference information only. Specific facts and circumstances may alter the concepts and applications of materials and information described herein. The information provided is not a substitute for professional advice and should not be relied upon in the absence of such professional advice specific to whatever facts and circumstances are presented in any given situation. Answers are correct at the time they are posted on the Web site. Be advised that over time, some requirements could change, new data could be made available, or Internet links could change. For answers that have been posted for several months or longer, please check the current status of the posted information prior to using the responses for specific applications

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Exhibit 2

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Sunburn

Last Updated: October 27, 2004

Synonyms and related keywords: sun burn, erythema solare, ultraviolet radiation, UVR

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AUTHOR INFORMATION

Section 1 of 10

Next

Author Information Introduction Clinical Differentials Workup Treatment Medication Follow-up
Miscellaneous Bibliography

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[Author Information](#)
[Introduction](#)
[Clinical](#)
[Differentials](#)
[Workup](#)
[Treatment](#)
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[Dermatitis, Contact](#)
[Dermatitis, Exfoliative](#)
[Heat Exhaustion and Heatstroke](#)
[Systemic Lupus Erythematosus](#)

INTRODUCTION

Section 2 of 10 [Back Top Next]

Author Information Introduction Clinical Differentials Workup Treatment Medication Follow-up
Miscellaneous Bibliography

Continuing Education

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Background: Sunburn is an acute cutaneous inflammatory reaction that follows excessive exposure of the skin to ultraviolet radiation (UVR). Long-term adverse health effects of repeated exposure to UVR

are well described but are beyond the scope of this article.

Pathophysiology: Exposure to solar radiation has the beneficial effects of stimulating the cutaneous synthesis of vitamin D and providing radiant warmth. Unfortunately, when the skin is subjected to excessive radiation in the ultraviolet range (wavelength <400 nm), deleterious effects may occur. The most common is acute sunburn or solar erythema.

Solar erythema is associated with microscopic changes in the skin, detectable within 30 minutes of exposure to UVR. The most characteristic changes include formation of epidermal sunburn cells, damaged keratinocytes with hyaline cytoplasm, and pyknotic nuclei. Epidermal Langerhans cell and mast cell numbers may decrease, while the relative percentage of hypogranulated or degranulated cells may increase. Superficial blood vessels show endothelial swelling, perivenular edema, and a mixed perivascular infiltrate.

The precise biochemical pathways that lead to the sunburn reaction are not well understood but appear to involve multiple inflammatory mediators, including histamine, prostaglandins, and cytokines.

Less intense or shorter-duration exposure to UVR results in an increase in skin pigmentation, known as tanning, which provides some protection against further UVR-induced damage. The increased skin pigmentation occurs in 2 phases, (1) immediate pigment darkening, and (2) delayed tanning. Immediate pigment darkening occurs during exposure to UVR and results from alteration of existing melanin (oxidation, redistribution). It may fade rapidly or persist for several days. Delayed tanning results from increased synthesis of epidermal melanin and requires a longer period of time to become visible (24-72 h). With repeated exposure to UVR, the skin thickens, primarily due to epidermal hyperplasia with thickening of the stratum corneum.

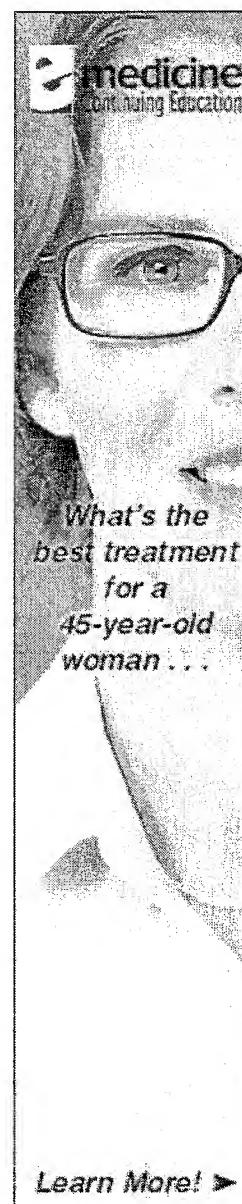
Frequency:

- **In the US:** Incidence is highest in areas with the highest flux of solar radiation (ie, the southern United States).
- **Internationally:** Incidence is increased in regions that are closer to the equator, that are higher in altitude, and where individuals have lighter baseline skin pigmentation.

Mortality/Morbidity:

- Uncomplicated sunburn is associated with minimal short-term morbidity. Most cases resolve spontaneously with no significant sequelae.

Patient Education
Burns Center
Sunburn Overview
Sunburn Causes
Sunburn Symptoms
Sunburn Treatment



- In rare cases, sunburn may be so severe and diffuse that it results in second-degree burns, dehydration, secondary infection, shock, or even death.
- Morbidity and mortality associated with long-term sun exposure is related primarily to the development of cutaneous neoplasms, including basal cell carcinoma, squamous cell carcinoma, and malignant melanoma.

Race: Lighter-skinned individuals are affected more frequently and severely. Skin types may be divided into 6 categories, based on an individual's tendency to tan and/or burn (see Table 1).

Table 1. Skin Phototypes

Skin Phototype	Description	Typical Features	MED	Minimum SPF
I	Always burns, never tans	White skin, blue/hazel eyes, blond/red hair	15-30 mJ/cm ²	≥15
II	Always burns, tans minimally	Fair skin, blue eyes	25-40 mJ/cm ²	≥15
III	Burns minimally, tans slowly	Darker Caucasian skin	30-50 mJ/cm ²	10-15
IV	Burns minimally, tans well	Light brown skin, Mediterranean	40-60 mJ/cm ²	6-10
V	Rarely burns, tans profusely/darkly	Brown skin, Middle Eastern, Latin American	60-90 mJ/cm ²	4-6
VI	Never burns, always tans, deeply pigmented	Dark brown or black skin	90-150 mJ/cm ²	None

Age: Most people get the majority of their sun exposure when young, making sunburn more common in children and young adults. Some elderly individuals have a blunted sunburn response.

CLINICAL	Section 3 of 10 [Back] [Top] [Next]
Author Information Introduction Clinical Differentials Workup Treatment Medication Follow-up Miscellaneous Bibliography	

History:

- Recent sun exposure or outdoor activity; outdoor occupations or hobbies
- Erythema develops after 2-6 hours and peaks at 12-24 hours.
- Pain
- Possible fever, chills, malaise, nausea, or vomiting in severe cases
- Blistering
- Erythema that resolves over 4-7 days, usually with skin scaling and peeling
- Assess for exposure to photosensitizing drugs.

Physical:

- Patients at highest risk typically have fair skin, blue eyes, and red or blond hair.
- Immediate or early erythema occurs during UVR exposure and fades within 30 minutes.
- The acute inflammatory response is greatest 20-24 hours after exposure.
 - Erythema
 - Warmth
 - Tenderness
 - Edema
 - Blistering (severe cases)
- Fever can present in severe cases.
- Most exposure is limited to sun-exposed areas of the body; however, significant transmission of UVR may occur through some clothing, resulting in sunburn on clothed skin.
- Delayed scaling and desquamation occurs 4-7 days after exposure.

Causes:

- The electromagnetic spectrum can be divided according to wavelength into ultraviolet (<400 nm), visible (400-760 nm), and infrared (>760 nm).
 - Sunburn is caused by excessive exposure of the skin to UVR.
 - The ultraviolet spectrum can be divided into ultraviolet A (UV-A), 320-400 nm; ultraviolet B (UV-B), 290-320 nm; and ultraviolet C (UV-C), 200-290 nm.
 - Solar UVR of wavelengths shorter than 290 nm is filtered out or absorbed in the outer atmosphere and is not encountered at sea level.
 - UV-B radiation is much more potent at inducing erythema than UV-A and is, therefore, the principal cause of sunburn (about 85%).
 - However, UV-A comprises the majority of UVR reaching the surface of the earth (about 90% at midday) and, therefore, accounts for a significant percentage of the immediate and long-term cutaneous effects of UVR.
- The minimal single dose of UVR (energy per unit area) required to produce erythema at an exposed site is known as the minimal erythema dose (MED). Moderate-to-severe sunburn occurs at 3-8 MEDs.
- Multiple factors influence UVR-induced erythema.
 - Wavelength: UV-B is more erythemogenic than UV-A. Multiple wavelengths may result in an additive effect.
 - Skin pigmentation: Compared with white-skinned individuals, moderately pigmented races require 3-5 times more UVR exposure to cause erythema; blacks require up to 30 times more. Facultative (induced) tanning increases MEDs by only 2-3 times.
 - Skin thickness
 - Hydration: UVR penetrates moist skin more effectively than dry skin.
 - Anatomic site: MEDs are greater on the limbs than on the face, neck, and trunk.
 - Environmental reflection: Radiation is 80% reflected by

snow and ice, compared to 20% by sand.

- Altitude: UVR increases 4% for every 300-m (1000-ft) increase in elevation.
- Latitude: Exposure is greater at lower latitudes.
- Time of day: 65% of UVR reaches the earth between 10 am and 2 pm.

DIFFERENTIALS	Section 4 of 10	[Back]	[Top]	[Next]
Author Information Introduction Clinical Differentials Workup Treatment Medication Follow-up Miscellaneous Bibliography				

[Burns, Chemical](#)
[Burns, Thermal](#)
[Cellulitis](#)
[Dermatitis, Atopic](#)
[Dermatitis, Contact](#)
[Dermatitis, Exfoliative](#)
[Heat Exhaustion and Heatstroke](#)
[Systemic Lupus Erythematosus](#)

WORKUP	Section 5 of 10	[Back]	[Top]	[Next]
Author Information Introduction Clinical Differentials Workup Treatment Medication Follow-up Miscellaneous Bibliography				

Lab Studies:

- None indicated for uncomplicated cases

Imaging Studies:

- None indicated for uncomplicated cases

Procedures:

- Skin biopsy may be useful if the diagnosis is in doubt or to exclude other diseases in the differential.

TREATMENT	Section 6 of 10	[Back]	[Top]	[Next]
Author Information Introduction Clinical Differentials Workup Treatment Medication Follow-up Miscellaneous Bibliography				

Prehospital Care:

- In most cases, prehospital care involves providing simple first aid to treat patient symptoms.
- In severe cases, patients may develop second-degree burns, which rarely require aggressive fluid resuscitation and skin care.

Emergency Department Care:

- Most sunburns, while painful, are not life threatening, and treatment is primarily symptomatic.
- Aspirin and nonsteroidal anti-inflammatory drugs (NSAIDs) have antiprostaglandin effects and are useful to relieve pain and inflammation, especially when given early. Cool soaks with water or Burow solution also provide temporary relief.
- Systemic steroids may shorten the course and reduce the pain of sunburn when given early and in relatively high doses (equivalent to 40-60 mg/d of prednisone).
 - When used, prescribe them for only a few days, with no need for a taper.
 - In the presence of severe second-degree burns, steroids are best avoided because they increase the risk of infection.
 - Topical steroids show minimal, if any, benefit.
- Severe cases may require treatment of accompanying dehydration or secondary infection.
 - Severe cases may be associated with other heat-related illnesses, including heat exhaustion and heat stroke.
 - In rare cases, patients may require admission to a burn unit for aggressive skin care, intravenous fluids, and electrolyte management. Shock can occur.
- Prophylaxis of sunburn may be possible if a patient is treated with systemic steroids, equivalent to a daily dose of 60-80 mg of prednisone (1.0-1.5 mg/kg), prior to or shortly following sun exposure.

Consultations:

- Consult a dermatologist if the diagnosis of sunburn is in doubt or for children who appear to burn easily. In the latter case, a more serious underlying disorder may be present.
- Severe cases may require consultation with pediatricians or internists for hospital admission. Patients rarely require care in a dedicated burn unit.

MEDICATION

Section 7 of 10 [Back Top Next]

Author information: [Introduction](#) [Clinical Differentials](#) [Workup](#) [Treatment](#) [Medication](#) [Follow-up](#) [Miscellaneous](#) [Bibliography](#)

Minor sunburn can be relieved to some extent with cool compresses or a cool bath. Administration of nonprescription analgesics and NSAIDs for the treatment of pain and inflammation is recommended.

Drug Category: Analgesics -- Pain control is essential to quality patient care. It ensures patient comfort and promotes pulmonary toilet. Most analgesics have sedating properties, which are beneficial for patients who have sustained sunburns.

Drug Name	Aspirin (Bayer, Anacin, Bufferin) -- Used for the treatment of mild to moderate pain. Also acts on the hypothalamus heat-regulating center to reduce fever.
Adult Dose	650 mg PO bid/tid/qid; not to exceed 4 g/d in equally divided doses
Pediatric Dose	10-15 mg/kg/dose q4-6h; not to exceed 60-80 mg/kg/d
Contraindications	Documented hypersensitivity; liver damage; hypoprothrombinemia; vitamin K deficiency; bleeding disorders; asthma; children (<16 y) with flu (because of association with Reye syndrome)
Interactions	Effects may decrease with antacids and urinary alkalinizers; corticosteroids decrease salicylate serum levels; additive hypoprothrombinemic effects and increased bleeding time may occur with coadministration of anticoagulants; may antagonize uricosuric effects of probenecid and increase toxicity of phenytoin and valproic acid; doses >2 g/d may potentiate glucose-lowering effect of sulfonylurea drugs
Pregnancy	D - Unsafe in pregnancy
Precautions	May cause transient decrease in renal function and aggravate chronic kidney disease; avoid use in patients with severe anemia, with history of blood coagulation defects, or taking anticoagulants
Drug Name	Ibuprofen (Advil, Motrin, Nuprin) -- Usually the DOC for the treatment of mild to moderate pain, if no contraindications are present.
Adult Dose	200-400 mg q4-6h while symptoms persist; not to exceed 3.2 g/d
Pediatric Dose	30-70 mg/kg/d tid/qid
Contraindications	Documented hypersensitivity; peptic ulcer disease; recent GI bleeding or perforation; renal insufficiency; high risk of bleeding
	Coadministration with aspirin increases risk of inducing serious NSAID-related adverse effects; probenecid may increase concentrations and, possibly, toxicity of NSAIDs;

Interactions	may decrease effect of hydralazine, captopril, and beta-blockers; may decrease diuretic effects of furosemide and thiazides; monitor PT closely (instruct patients to watch for signs of bleeding); may increase risk of methotrexate toxicity; phenytoin levels may be increased when administered concurrently
Pregnancy	B - Usually safe but benefits must outweigh the risks.
Precautions	Category D in third trimester of pregnancy; caution in congestive heart failure, hypertension, and decreased renal and hepatic function; caution in anticoagulation abnormalities or during anticoagulant therapy
Drug Name	Acetaminophen (Tylenol, Aspirin Free Anacin, Feverall) -- DOC for treatment of pain in patients with documented hypersensitivity to aspirin, upper GI disease, or oral anticoagulants.
Adult Dose	325-650 mg q4-6h or 1000 mg tid/qid; not to exceed 4 g/d
Pediatric Dose	<12 years: 10-15 mg/kg/dose q4-6h prn; not to exceed 2.6 g/d >12 years: 325-650 mg q4h; not to exceed 5 doses in 24 h
Contraindications	Documented hypersensitivity; G-6-PD deficiency
Interactions	Rifampin can reduce analgesic effects of acetaminophen; coadministration with barbiturates, carbamazepine, hydantoins, and isoniazid may increase hepatotoxicity
Pregnancy	B - Usually safe but benefits must outweigh the risks.
Precautions	Hepatotoxicity possible in chronic alcoholics following various dose levels; severe or recurrent pain or high or continued fever may indicate serious illness; acetaminophen is contained in many OTC products and combined use with these products may result in cumulative acetaminophen doses exceeding recommended maximum dose

Drug Category: Corticosteroids -- Have anti-inflammatory properties and cause profound and varied metabolic effects. Corticosteroids modify the body's immune response to diverse stimuli. May shorten the course and reduce the pain of sunburn.

Drug Name	Prednisone (Deltasone, Orasone, Meticorten) -- May decrease inflammation by reversing increased capillary permeability and suppressing PMN activity.
Adult Dose	40-60 mg/d PO
Pediatric Dose	1 mg/kg PO qd
Contraindications	Documented hypersensitivity; viral infection, peptic ulcer disease, hepatic dysfunction, connective tissue infections, and fungal or tubercular skin infections; GI disease

Interactions	toxicity secondary to hypokalemia; phenobarbital, phenytoin, and rifampin may increase metabolism of glucocorticoids (consider increasing maintenance dose); monitor for hypokalemia with coadministration of diuretics
Pregnancy	B - Usually safe but benefits must outweigh the risks.
Precautions	Abrupt discontinuation of glucocorticoids may cause adrenal crisis; hyperglycemia, edema, osteonecrosis, myopathy, peptic ulcer disease, hypokalemia, osteoporosis, euphoria, psychosis, myasthenia gravis, growth suppression, and infections may occur with glucocorticoid use

FOLLOW-UP

Section 8 of 10 [\[Back\]](#) [\[Top\]](#) [\[Next\]](#)

Author information: Introduction Clinical Differentials Workup Treatment Medication Follow-up Miscellaneous Bibliography

Further Inpatient Care:

- Inpatient care is indicated for severe burns, secondary infection, or control of severe pain.
- Indications for admission to a dedicated burn unit are the same as those for thermal burns.

Further Outpatient Care:

- Outpatient care is indicated for most cases of sunburn.
 - Cool baths or showers
 - Anti-inflammatory/analgesic medications
 - Avoidance of further sun exposure

In/Out Patient Meds:

- Topical anesthetic sprays or creams may cause sensitization and consequent dermatitis and, therefore, should be avoided.

Transfer:

- Only the most severe cases of sunburn, with marked involvement of a large percentage of the body surface area, require transfer to a burn unit for treatment.

Deterrence/Prevention:

- Prevention is the most effective therapy for sunburn. Individual and community educational programs can be effective in decreasing overall sun exposure or increasing use of sunscreen or protective clothing.

- Avoid sun exposure, especially during the period of peak solar radiation flux (from 10 am to 2 pm).
- Wear protective clothing, including hats or sun visors.
- Regularly use sunscreens with an adequate sun protection factor (SPF) for a given skin type (see *Race*).
 - SPF refers to the time needed to produce erythema on protected skin as a factor of the time to produce erythema on unprotected skin.
 - In general, use of a sunscreen with an SPF of 30 is sufficient.
 - Apply at least 30 minutes prior to sun exposure and reapply often.
 - Use waterproof sunscreens when swimming or perspiring heavily.
 - Physical barriers (eg, zinc oxide, talc, titanium dioxide) provide excellent protection but are less appealing cosmetically.
 - Chemical barriers are used in most sunscreens. Para-aminobenzoic acid (PABA) and PABA esters, which diffuse into stratum corneum and bind, are used most commonly, but they may stain clothing or produce contact dermatitis. Other chemical blocking agents include cinnamates, salicylates, anthranilates, and benzophenones. Many sunscreens employ a combination of agents.

Complications:

- Sunburns can exacerbate other skin diseases.
- Sunburns may trigger recurrence of herpes simplex, lupus, porphyria, or other cutaneous disorders.
- Sunburns may be associated with other heat-related illnesses, including dehydration, heat exhaustion, and heatstroke.
- Long-term exposure of the skin can lead to multiple deleterious effects, including premature aging and wrinkling of the skin (dermatoheliosis), development of premalignant lesions (solar keratoses), and development of malignant tumors (eg, basal cell carcinoma, squamous cell carcinoma, melanoma).
- Excessive exposure of the eyes to UVR can lead to discoloration of the lens and nuclear cataract formation.
- Photokeratoconjunctivitis, or snow blindness, may exist concurrently with sunburn.

Prognosis:

- Uncomplicated cases of sunburn resolve spontaneously over 4-7 days with scaling and

desquamation but without acute sequelae.

- Long-term exposure to UVR is associated with several deleterious effects on the skin, as delineated above.

Patient Education:

- Short- and long-term complications (see Complications)
- Prevention (see Deterrence/Prevention)
- For excellent patient education resources, visit eMedicine's Burns Center. Also, see eMedicine's patient education article Sunburn.

MISCELLANEOUS		Section 9 of 10 [Back] [Top] [Next]
Author Information Introduction Clinical Differentials Workup Treatment Medication Follow-up Miscellaneous Bibliography		

Medical/Legal Pitfalls:

- Since window glass blocks UV-B, patients presenting with solar reactions occurring from exposure through window glass should be evaluated for phototoxic reactions and porphyria.
- Easy sunburning during infancy may indicate a serious underlying disease, such as porphyria or xeroderma pigmentosum. Referral for further evaluation is prudent.
- Obtain a complete drug exposure history in any patient with a rash.

Special Concerns:

- Avoid use of PABA and PABA esters on children younger than 6 months.

BIBLIOGRAPHY		Section 10 of 10 [Back] [Top]
Author Information Introduction Clinical Differentials Workup Treatment Medication Follow-up Miscellaneous Bibliography		

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